

JUN 13 2002



2005 Manhattan Beach Boulevard  
Redondo Beach, CA 90278-1205

TEL (800) 624-8380 or (310) 536-0006  
FAX (800) 845-1834 or (310) 536-9977

### 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K021393

<b>Proprietary Name:</b>	Preciset® DAT Plus
<b>Common Name:</b>	Calibrators/Controls
<b>Classification Name:</b>	Calibrators, Drug Mixture
<b>Medical specialty:</b>	Clinical Toxicology
<b>Product Code:</b>	DKB
<b>Device class:</b>	2
<b>Regulation No:</b>	862.3200
<b>Manufacturer:</b>	Quantimetrix Corporation 2005 Manhattan Beach Boulevard Redondo Beach CA 90278 Phone: 310/536-0006 FAX: 310/536-9977
<b>Contact Persons:</b>	Gebhard Neyer, Ph.D., Director of R&D, 310-536-0006
<b>Registration No:</b>	2020715

The Quantimetrix Preciset® DAT Plus drug of abuse calibrator is supplied liquid in a glass bottle. It consists of drug-free human urine to which preservative, stabilizer and drugs of abuse have been added to achieve six distinct levels. The drugs added are:  
*metamphetamine, nordiazepam, barbiturates, cocaine/cocaine metabolites, methadone, morphine, phencyclidine, propoxyphene, cannabinoids*

Drug concentrations are determined using GC/MS.

Quantimetrix Corp.

The Quantimetrix calibrator is substantially equivalent to the currently marketed **Emit® Calibrators/controls** manufactured by **Syva Company**.

Both feature similar matrices, constituents and stability claims.

#### **Intended Use**

The Preciset DAT Plus calibrators are designed for the calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.

#### **Performance Characteristics**

Accelerated stability studies (25°C and 37°C) and real time studies were performed to validate the shelf life claim and the opened vial claim of the calibrators.

When tested with the Roche immunoassays (currently under development) the calibrators were found to perform well and to be sufficiently stable for their intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

**JUN 13 2002**

Dr. Gebhard Neyer  
Director, Research & Development  
Quantimetrix Corporation  
2005 Manhattan Beach Boulevard  
Redondo Beach, CA 90278-1205

Re: k021393  
Trade/Device Name: Preciset® DAT Plus  
Regulation Number: 21 CFR 862.3200  
Regulation Name: Clinical toxicology calibrator  
Regulatory Class: Class II  
Product Code: DKB  
Dated: May 1, 2002  
Received: May 2, 2002

Dear Dr. Gebhard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 -

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

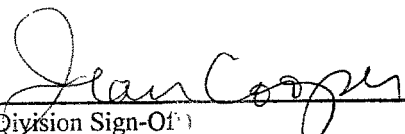
Enclosure

510(k) Number (if known): K021393

Device Name: Preciset® DAT Plus  
Drug of Abuse Calibrators

### Indications For Use:

The Preciset DAT Plus calibrators are designed for the calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K021393

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

OR

Over-The-Counter Use \_\_\_\_\_

(Per 21 CFR 801.109)

(Optional Format 1-2-96)